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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,083	02/04/2004	Daniel J. Cua	DX06023 US 01	3286

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DNAX RESEARCH, INC.
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EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,083

Applicant(s)

CUA ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 3, 4, 5 and 8-10, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a nucleic acid agonist of IL-23, classifiable in class 514, subclass 44.
- II. Claims 1, 2, 3, 4, 5, 8-10, 12, 13 and 15, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a nucleic acid antagonist of IL-23 wherein the antagonist inhibits activation of a resident microglial cell, classifiable in class 514, subclass 44.
- III. Claims 1, 2, 3, 4, 5, 8-10, 12, 13 and 16-17, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a nucleic acid antagonist of IL-23 wherein the antagonist inhibits expression of a macrophage, classifiable in class 514, subclass 44.
- IV. Claims 1, 2, 3, 4 and 8-10, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a small molecule agonist of IL-23, classifiable in class 514, subclass 44.
- V. Claims 1, 2, 3, 4, 8-10, 12, 13 and 15, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a small molecule antagonist of IL-23 wherein the antagonist inhibits activation of a resident microglial cell, classifiable in class 514, subclass 44.

- VI. Claims 1, 2, 3, 4, 8-10, 12, 13 and 16-17, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a small molecule antagonist of IL-23 wherein the antagonist inhibits expression of a macrophage, classifiable in class 514, subclass 44.
- VII. Claims 1, 2 and 6-10, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of an antigen binding fragment of an antibody or a soluble receptor agonist of IL-23, classifiable in class 514, subclass 44.
- VIII. Claims 1, 2, 6-10, 12, 13 and 15, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of an antigen binding fragment of an antibody or a soluble receptor antagonist of IL-23 wherein the antagonist inhibits activation of a resident microglial cell, classifiable in class 514, subclass 44.
- IX. Claims 1, 2, 6-10, 12, 13 and 16-17, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of an antigen binding fragment of an antibody or a soluble receptor antagonist of IL-23 wherein the antagonist inhibits expression of a macrophage, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.
- X. Claims 1, 2, 3, 4, 5 and 8-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a nucleic acid agonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.

- XI. Claims 1, 2, 3, 4, 5 and 8-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a nucleic acid antagonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.
- XII. Claims 1, 2, 4 and 8-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a small molecule agonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.
- XIII. Claims 1, 2, 4 and 8-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of a small molecule antagonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.
- XIV. Claims 1, 2 and 6-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of an antigen binding fragment of an antibody or a soluble receptor agonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.
- XV. Claims 1, 2 and 6-13, drawn to a method of treating an IL-23 mediated disorder comprising administering an effective amount of an antigen binding fragment of an antibody or a soluble receptor antagonist of IL-23 and a cytokine, classifiable in class 514, subclass 44. This group is subject to a further restriction as per below.

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XVI. Claims 18-19, drawn to a purified or isolated IL-17 producing CD4+ T cell, classifiable in class 435, subclass 326.

XVII. Claim 20, drawn to a method of generating an IL-17 producing CD4+ cell, classifiable in class 435, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-IX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of groups I, IV, VII and X are drawn to administering an agonist of IL-23, which is materially different than the methods of group II, III, IV, VI, VIII, IX and XI, which are drawn to administering an antagonist of IL-23. Additionally, the methods of groups I-III are drawn to administering a nucleic acid agonist or antagonist, which is an entirely different molecule than the small molecule agonist of groups IV-VI and the antigen binding fragment or soluble receptor agonist or antagonist of groups VII-IX. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-IX and groups X-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of groups I-IX are drawn to administering a nucleic acid, small molecule, antigen binding fragment or soluble receptor agonist or antagonist of IL-23, which have a materially different function and mode of operation than co-administering the above agonist or antagonist along with an agonist or antagonist of a cytokine, as present in groups X-XV. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-IX and group XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the purified or isolated IL-17 CD4+ T cell line is not disclosed as useful in the methods of groups I-IX, which are drawn to administering a nucleic acid, small molecule, antigen binding fragment or soluble receptor agonists or antagonists of IL-23. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-IX and group XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of groups I-IX are drawn to treating an IL-23 mediated disorder, which is not disclosed as capable of use together and is materially different than the method of group XVII, which is drawn to producing a CD4+ T cell line. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups X-XV and group XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the purified or isolated IL-17 CD4+ T cell line is not disclosed as useful in the methods of groups X-XV, which are drawn to co-administering a nucleic acid, small molecule, antigen binding fragment or soluble receptor agonists or antagonists of IL-23 along with a cytokine to treat an IL-23 mediated disorder. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups X-XV and group XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of groups X-XV are drawn to treating an IL-23 mediated disorder, which is not disclosed as capable of use together and is materially different than the method of group XVII, which is drawn to producing a CD4+ T cell line. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups XVI and group XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of group XVI is drawn to an IL-17 producing T cell, which is not disclosed as capable of use in the method of group XVII which is drawn to a method of producing an IL-17 producing T cell comprising contacting a T cell with IL-23. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Furthermore, should applicants elect to prosecute groups X-XIII, these groups are subject to a further restriction as follows. Claim 11 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In *re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claim 11 specifically claims cytokines IL-12, IFN γ , IL-6, IL-17 and IL-10. Although the cytokines are all involved in the pathology and repair of neurological disorders, the instant cytokines are considered to be unrelated, since each cytokine claimed is structurally and functionally independent and distinct for the following reasons: each cytokine has a unique sequence and each cytokine has a different function and effect on an IL-23 mediated disorder. As such the Markush/genus of cytokines in claim 11 is not considered to constitute a proper genus,

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and are therefore subject to restriction. Furthermore, a search of more than one (1) of the cytokines claimed in claim 11 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed cytokines. In view of the foregoing, one (1) cytokine is considered to be a reasonable number of cytokines for examination. Accordingly, applicants are required to elect a total of one (1) cytokine from claim 11. Note that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Kimberly Chong
Examiner
Art Unit 1635

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